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10/076,170	02/11/2002	Shaorong Liu	1093/204	2824

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EXAMINER	
BARTON, JEFFREY THOMAS	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,170	LIU ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20030124*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 5, 9-11, and 15-17 are objected to because the electrodes, as described in the specification, are not truly electrolysis-free. For instance, on page 10, at lines 10-11, a bubble-free electrode is employed "to prevent electrolysis and bubble formation in or close to the microfluidic channels", which allows for some degree of electrolysis to occur. Also, at page 11, at lines 4-5, it is acknowledged that electrolysis occurs and bubbles form within the electrode structures of the device. It appears that the design of the electrodes leads to isolation of electrolysis and its associated products from the channels and other fluids of the system, but does not prevent electrolysis altogether. This being the case, any prior-art electrodes that avoid introduction of bubbles or other electrolysis products into the channels and meet other claim limitations will be considered to read on the claims. Appropriate correction is required.

Also, relevant to claim 1, no objection is specifically made, but in the absence of any specific disclosure describing a "coupler" in the instant specification, any means that provides connection of the electrodes to the fluids of the system (e.g. wires, channels) is viewed as reading on the limitations, because they provide the potential that causes fluid movement.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5, 9-11, and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding the limitation in claim 5, "without inducing electrolysis in the second electrode reservoir", at Page 11, lines 4-11 support is found for no electrolysis occurring at the tip of a connecting tube (29), but no support can be found for no electrolysis occurring in the electrode reservoir (36). The claims are treated herein as allowing electrolysis in the electrode reservoir, but not allowing electrolysis products to reach the device channels.

Furthermore, for claims 9-11, 15, and 16, it is not clear how the ion-transferring compound described in lines 4-5 of claim 9 can transfer ions, but not allow electrons to be transferred through it. Is the compound conductive? If so, the flow of ions carries with it a net flow of electrons, required for electrical conductance. If the compound is not conductive, given the illustration of Figures 2a and 3b (which seem to correspond to this embodiment), it is not clear how the electrode can function.

The claims are treated herein as corresponding to the embodiment described at Page 10, lines 10-18, wherein the compound has the properties of a conductive gel.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-6, 9, 11, 14, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Parce.

Regarding claim 1, Parce discloses a microfluidic system comprising: a substrate (Column 6, lines 17-18); a fluid network fabricated on the substrate (Figure 2), comprising two segments in fluid communication (First segment runs from reservoir 218 to 216, second segment is branch 104); an electrical source (116) coupled across the first segment to apply an electrical potential to induce electroosmotic flow in the first segment (Column 8, lines 10-27); a coupler directing electric potential from the electrical source to the first segment and directing flow between the segments, wherein flow in the second segment is caused by electroosmotic flow in the first segment. (Wires, electrodes and channels all perform this function)

Regarding claim 2, Parce discloses a fluid network comprising channels. (Figure 2)

Regarding claim 3, Parce discloses the first segment comprising a plurality of parallel channels. (Column 8, lines 49-53)

Regarding claim 4, Parce discloses electrode reservoirs (216, 218) at either end of the first segment, and the second end of the first segment being fluid coupled to the second segment (Figure 2)

Regarding claim 5, Parce discloses electrode construction that avoids electrolysis products being introduced into the channels of the system (Column 7, line 66 - Column 8, line 15), as in the electrodes described in the instant specification, making them "electrolysis-free" to the same degree as the claimed electrodes. More specifically, the structure of Parce's Figure 2 corresponds to that of the electrode of instant Figure 3b (aside from the tubing joint), with Parce's gel 204, reservoir 216, and electrode 114 corresponding to the gel in joint 30/tube 29, reservoir 36, and electrode 34. Similar correspondence exists between Parce's Figure 2 and instant Figure 2a, with a gel membrane in place of membrane 20.

Regarding claim 6, the joint that connects reservoir 216 to channel 202 would be bubble free, given the disclosed geometry. (Column 7, line 66 - Column 8, line 15)

Relevant to claim 9, Parce discloses the electrode comprising a protective housing (the plates, themselves; Column 4, line 57 - Column 5, line 25) and an ion-transferring compound. (Gel; Column 8, lines 35-49) Because the instant application regards the "electrode" as including the structure that surrounds the actual metal that

makes contact with the solution (e.g. Figure 3b; Page 10, lines 2-20), the electrodes of prior art networks are also viewed as including any surrounding structure.

Relevant to claims 11 and 15, Parce discloses the ion-transferring compound comprising polymeric agarose or polyacrylamide. (Column 8, lines 44-49)

Regarding claim 14, Parce discloses the system comprising a pipette. (Column 5, lines 46-49)

Relevant to claim 17, the gel plug used by Parce can be described as a membrane that allows ions, but not fluid, to pass through.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parce in view of Dasgupta et al.

Parce discloses a system as described above in addressing claim 1. Parce also discloses the use of pumps according to his invention in systems where fluid flow is caused in channels at a distance from the pumping channels/electrodes. (Column 5, lines 40-54)

Parce does not explicitly disclose a system wherein the second segment comprises an isolation channel preventing contamination between the first and second segment.

Dasgupta et al disclose an electroosmotic pumping system (Figure 1) wherein the pump fluid (in capillaries 22, 26) is separated from the "pumped" fluid of interest (in syringe 46, valve 40, and capillary 42) by an isolation channel (holding coil 34) that prevents contamination of fluids by each other. (Column 7, lines 37-44)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Parce by providing an isolation channel between the first and second segments to prevent mixing of the fluids, as taught by Dasgupta et al, because it would allow selection of a pumping fluid to optimize electroosmotic flow characteristics (Dasgupta et al, column 4, lines 25-36), without concern over interactions/contamination of the object fluid.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parce in view of Jacobson et al (*Anal. Chem.* reference).

Parce and Jacobson et al (U.S. 6,685,809) disclose a combined system as described above in addressing claim 9.

Neither Parce nor Jacobson et al (U.S. 6,685,809) explicitly disclose the electrode comprising a protective housing that comprises flexible tubing.

Jacobson et al (*Anal. Chem.* reference) disclose a microfluidic network comprising electrode reservoirs comprising flexible tubing. (Page 1108, last sentence of the 1st paragraph of the Experimental Section) A plastic cylinder can be considered flexible tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combined system of Parce and Jacobson et al (U.S. 6,685,809) by providing electrodes comprising flexible tubing, as taught by Jacobson et al (*Anal. Chem.* reference), because it would increase reservoir capacity, thus reducing effects of solvent evaporation and generation of electrolysis products.

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parce in view of Jacobson et al (US 6,685,809).

Parce discloses a microfluidic system as described above.

Parce does not explicitly disclose using a polymer gel plug of any of the specific listed compositions.

Jacobson et al disclose a polymer gel plug with the same function as that used by Parce, comprising 10% linear polyacrylamide. (Column 9, lines 63-66)
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Parce by using a polymer gel plug comprising grater than 1% polyacrylamide, as taught by Jacobson et al, because Parce discloses its use in resisting fluid flow (Column 8, lines 44-49), and gels with higher polyacrylamide percentages are known to have higher flow resistance.

11. Claims 1-7, 9, 11, 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barenburg et al in view of Parce.

Barenburg et al disclose a microfluidic system (Figure 16, 314; Column 27, line 54 - Column 28, line 35) comprising: a substrate (Visible in Figures 1-3); a fluid network disposed on the substrate comprising first and second segments in fluid communication (Column 31, line 43 - Column 32, line 25; first segment would be an electroosmotic pump, second segment would be channels/chambers with fluids of interest); and a coupler directing flow between the first and second segments, wherein fluid movement

is caused in the second segment by electroosmotic flow in the first segment. (Column 31, lines 37-55; Column 32, lines 11-19)

Regarding claim 7, Barenburg et al disclose valves in fluid communication with the second segment, wherein the valve routes fluids from the second segment to one of a plurality of output channels. (Column 33, lines 12-26)

Barenburg et al do not disclose particulars of the electroosmotic pumps used in their system, including electrode positioning, instead suggesting the suitability of a broad range of on-chip and off-chip pumps. (Column 31, line 43 - Column 32, line 25)

Parce et al disclose an electroosmotic pump described above in addressing claims 1-6, 9, 11, 14, 15, and 17.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Barenburg et al by incorporating the on-chip electroosmotic pump of Parce as a system pump, because Barenburg et al suggest the general suitability of pumps of this type, and Parce suggests the usefulness of his pumps in other microfluidic devices. (Column 5, lines 40-54)

12. Claims 1-7, 9, 11, 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jedrzejewski et al in view of Parce.

Jedrzejewski et al disclose a microfluidic system (Figure 1) comprising: a substrate (Figure 1); a fluid network disposed on the substrate comprising first and second segments in fluid communication (Figure 1, Column 23, lines 8-39; first segment would be an electroosmotic pump, second segment would be channels/chambers with

fluids to be moved); and a coupler directing flow between the first and second segments, wherein fluid movement is caused in the second segment by electroosmotic flow in the first segment. (Channels between fluids; Column 22, line 66 - Column 23, line 13)

Regarding claim 7, Jedrzejewski et al disclose valves in fluid communication with the second segment, wherein the valve routes fluids from the second segment to one of a plurality of output channels. (e.g. Figure 20; Column 22, lines 37-42; valves described generally in columns 16-24)

Jedrzejewski et al do not disclose particulars of the electroosmotic pumps used in their system, including electrode positioning, instead suggesting the suitability of a broad range of pumps, specifically describing electroosmotic pumps. (Column 23, lines 8-27)

Parce et al disclose an electroosmotic pump described above in addressing claims 1-6, 9, 11, 14, 15, and 17.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Jedrzejewski et al by incorporating the on-chip electroosmotic pump of Parce as a system pump, because Jedrzejewski et al suggest the general suitability of pumps of this type, and Parce suggests the usefulness of his pumps in other microfluidic devices. (Column 5, lines 40-54)

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Barenburg et al or Jedrzejewski et al in view of Parce, as applied to claim 1 in paragraphs 11 and 12 above, and further in view of Dasgupta et al.

The reasoning for these combinations parallels that given in paragraph 8 above.

14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Barenburg et al or Jedrzejewski et al in view of Parce, as applied to claim 9 in paragraphs 11 and 12 above, and further in view of Jacobson et al. (*Anal. Chem.* reference)

The reasoning for this combination parallels that given in paragraph 9 above.

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Barenburg et al or Jedrzejewski et al in view of Parce, as applied to claim 11 in paragraphs 11 and 12 above, and further in view of Jacobson et al. (U.S. 6,685,809)

The reasoning for this combination parallels that given in paragraph 10 above.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
December 2, 2004

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